

FIG. 1

Study Setup

Clinical Study Definition

- Describes Sponsors & Investigators
- Declares Subject Attributes to Capture
- Associates Specific Lab Procedures with a Clinical Study
- Defines Genotype Results to Report

Study Protocols

Sponsor Information:
 Sponsor Company: A Co.
 Sponsor Representative: John Doe, Ph.D.
 Sponsor Study No: 198-005
 Study No: 832-001

Investigators:
 John Doe, Ph.D.

Protocol Information:
 Protocol Title: Pharmacokinetic Evaluation of Oros(R) (oxycodone hydrochloride) and IR oxycodone administered alone and in the presence of ketoconazole.
 PPVx Protocol Title: Genomic DNA isolation and molecular genotyping analysis of CYP2D6 "A", "B", "D", "E", "G", and "T" alleles.

Subject Attributes:
 Subject Number: [Field]
 Gender: [Field]
 Birthdate: [Field]
 Ethnicity: [Field]

Procedures:
 DNA Isolation, 3 mL whole blood, Purgene Kit
 SpectroMax DNA quantitation
 CYP2C9*3
 CYP2C9*2 Ver. 7

Final Storage Tube Range (*): [Field]

Barcode Information:
 Cascade Accession Number: [Field]
 Barcode Length: [Field]

Buttons:
 Define Results, New, Modify, Delete, Save, Cancel, Close

Created/Modified:
 Created: DNALIMS 10/4/98 12:02
 Modified: DNALIMS 10/5/98 14:38

Fig. 2

Accessioning

Clinical Sample Registration

- Provides Validation Checks for Accession & Tube ID's
- Accommodates Multiple Sample Tubes
- Enforces Controlled Subject Attribute Terms
- Supports Sample Workflow

Accessioning

| Study No. | Accession No. | Sponsor Sample Tube ID | Sample Tube ID | Received Date | Location |
|-----------|---------------|------------------------|----------------|---------------|----------|
| 632-001 | A100123 | BA10112 | PS22156 | 09-OCT-1999 | |
| 632-001 | A100124 | BA10113 | PS22157 | 09-OCT-1999 | |
| 632-001 | A100125 | BA10114 | PS22158 | 09-OCT-1999 | |
| 632-001 | A100126 | BA10115 | PS22159 | 09-OCT-1999 | |

PPGx Study No: **632-001** Sponsor: **A Co. (John Doe, Ph.D.)**
 Accession No: **A100126** Date Received: **09-Oct-1999** Sample Type: **Fresh Whole Blood**

Tube 1: Sponsor Sample Tube ID: **BA10115** PPGx Sample Tube ID: **PS22159** Sample Tube Volume: **>=5** Sample Condition: **Good**
 Tube 2: **BA10115** **PS22159** **>=5** **Good**
 Tube 3: **BA10115** **PS22159** **>=5** **Good**
 Tube 4: **BA10115** **PS22159** **>=5** **Good**

Comments:
 Subject Attributes:
 Subject Number: **15678**
 Gender: **M**
 Birthdate: **18-Sep-88**
 Ethnicity: **Black**

Add Comments:
 Created: **10/9/99 20:03** Modified:
 ID: **DNALIMS**

Print:
 Save As a Worksheet:
 Query:
 Place Samples:
 New:
 Delete:
 Modify:
 Save:
 Cancel:
 Close:

Fig. 3

Sample Tracking

- ◆ Supports Multiple Container Classes
- ◆ Allows User Defined Container Geometries & Templates
- ◆ Maintains Sample & Container Location
- ◆ Permits Flexible Sample Loading & Rearrangement
- ◆ Tracks and Maintains Container & Sample Ownership

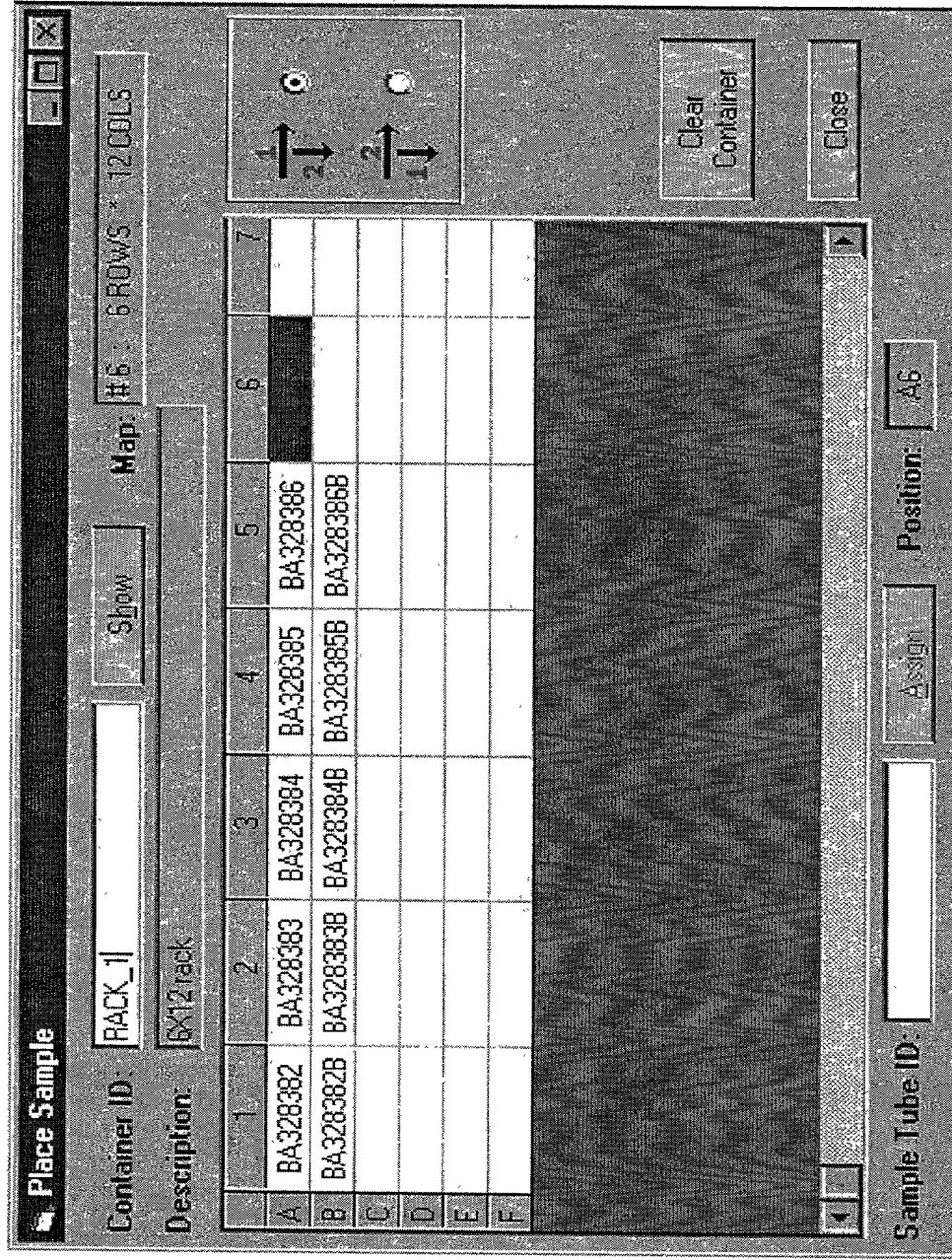


Fig. 4

Worklists

| Worklist Name | Assigned To | Created By | Created On | Mo |
|--------------------|-------------|------------|---------------|----|
| POC1005 | DNALIMS | DNALIMS | 10/5/99 13:54 | DN |
| PST SAMPLES | DNALIMS | DNALIMS | 10/6/99 08:02 | DN |
| TODAY'S GENOTYPING | DNALIMS | DNALIMS | 10/6/99 17:47 | DN |

Worklist Name: PST SAMPLES **Assigned To:** DNALIMS

Samples

| Sample Tube ID | Accession # | PPGx Study No. | Location |
|----------------|-------------|----------------|-----------------------|
| S1 | A1 | PS1 | Fr.1 Comp. Shelf Rack |
| S2 | A2 | PS1 | Fr.1 Comp. Shelf Rack |
| S3 | A3 | PS1 | Fr.1 Comp. Shelf Rack |
| S4 | A4 | PS1 | Fr.1 Comp. Shelf Rack |
| S5 | A5 | PS1 | Fr.1 Comp. Shelf Rack |

Containers

Created: DNALIMS **Modified:** DNALIMS **10/6/99 08:02** **10/7/99 08:50**

Fig. 5

- ## Sample Worklists
- ◆ Named Sample Collections
 - ◆ Assignable to Lab Scientists
 - ◆ Groups Samples for Common Lab Operations
 - Location
 - Check-in/Check-out
 - Lab Procedures

[illegible]

- Supports Standard Operating Procedures
- Maintains Uniform Laboratory Processes
- Records Chain of Custody
- Tracks Repeat Operations

Fig. 6

Fig. 6

PROCEDURES

| Procedure | Status | SOP Number | SOP Version |
|--|----------|------------|-------------|
| DNA Isolation, 3 mL whole blood, Purgene Kit | APPROVED | GEN9709 | C |
| 2D6 Allele "A" Identification | APPROVED | CYP2D6A | A |
| SpectroMax DNA quantitation | APPROVED | MAX9802 | A |
| CYP2C9*3 | APPROVED | CYP2C9-3 | A |
| CYP2C9*2 Ver. 7 | APPROVED | CYP2C9-2 | A |
| CYP2C9*2 Ver. 6 | APPROVED | CYP2C9-2 | A |

Procedure Name:

2D6 Allele "A" Identification

Procedure Description:

Laboratory Protocol for Identification of CYP2D6 "A" Allele by RFLP/PCR

Print

Save As ...

Genes:

Alleles:

SOP Number:

CYP2D6A

SOP Version:

A

Status:

APPROVED

New

Save

Modify

Cancel

Delete

Close

Created

DNALIMS

10/4/99 12:02

Modified

DNALIMS

10/5/99 10:59

Fig. 7

Procedure Steps

- ◆ A Single Step in a Lab Procedure
- ◆ Multiple Types:
 - Transfer
 - Dilution
 - Concentration Adjustment
 - Sample Preparation
- ◆ Highly Customizable
- ◆ Plug-in Architecture to Add New Types
- ◆ Interfaces to Automation

Procedure Steps

Procedure: DNA Isolation, 3 mL whole blood, Purgene Kit

| Step | Step Input Type | Functional Type | Level |
|--|-----------------|------------------|-------|
| Thaw frozen blood | CheckBox | | Batch |
| Gently mix sample | CheckBox | | Batch |
| Transfer 3 mL of blood to Lysis tube | Functional | Transfer | Batch |
| Add 9 mL of RBC lysis to RBC lysis tube | Functional | Reagent Addition | Batch |
| Mix and incubate 10 minutes at room temperature | CheckBox | | Batch |
| Centrifuge 10 minutes at 3000RPM | Text | | Batch |
| Pour off supernatant into biohazardous waste container | CheckBox | | Batch |
| Resuspend cell pellet by vortexing | CheckBox | | Batch |
| Add 3 mL of Cell Lysis Solution | Functional | Reagent Addition | Batch |
| Sample can be stored for 18 months at RT in Cell L | Informational | | Batch |
| STOP POINT | Informational | | Batch |

Step: Add 9 mL of RBC lysis to RBC lysis tube

Step Level: ☒ Sample ☐ Batch

Step Type: ☒ Informational ☐ CheckBox ☐ Text

Reagent Addition:

| | |
|-----------------|---------------|
| Volume | 9000 |
| To final volume | FALSE |
| Reagent name | RBC Lysis Sol |
| Reagent prefix | RL |
| Volume optional | |
| Wave scanning | TRUE |
| Lock parameters | TRUE |

Save Sequence

New Delete Modify Close

Created: DNA LIMS 10/5/99 05:00 Modified: DNA LIMS 9/30/99 14:42

Fig. 8

Results

| Study Protocol | Accession No. | Status |
|----------------|---------------|-------------|
| PS1 | A3 | OPEN |
| PS1 | A4 | OPEN |
| PS1 | A5 | OPEN |
| PS1 | A6 | OPEN |
| PS1 | A7 | OPEN |
| PS1 | A8 | OPEN |
| PS1 | A9 | OPEN |

Study Protocol: PS1
Sponsor: C. Co., David Jones
Investigators:

Accession No: A6 Status: OPEN

Genotyping | DNA Purification | Chain Of Custody |

| GENE | Status | Interpretation | Exclude | Final GT | Entered By | Entered On |
|--------|----------|-----------------------|--------------------------|----------|------------|--------------|
| CYP2C9 | COMPLETE | EXTENSIVE METABOLIZER | <input type="checkbox"/> | wt/wt | DNALIMS | 10/6/99 6:48 |

Gene: CYP2C9

| Allele | Result | Batch | Procedure | Created By | Created On | Entered |
|--------|--------|-------|----------------|------------|--------------------|---------|
| m2 | mt/wt | Batch | CYP2C9*2 Ver 7 | DNALIMS | 10/6/99 6:09:48 PM | DNALI |
| m2 | mt/wt | Batch | CYP2C9*2 Ver 7 | DNALIMS | 10/6/99 6:09:48 PM | |
| m2 | mt/wt | Batch | CYP2C9*2 Ver 7 | DNALIMS | 10/6/99 6:09:48 PM | |

FINAL RESULT

Genotype Results

- ◆ Accommodates Values for Multiple Genes, Alleles & Assays
- ◆ Provides Master Review by Accession Number
- ◆ Supports Acceptance & Final Approval by Study Director
- ◆ Imports Results Electronically or Manually

Fig. 9

Auditing

- ◆ Track Changes in Database
 - Study
 - Lab Procedures
 - Sample
 - Results
- ◆ Flexible Audit Reporting
- ◆ Chain of Custody by Accession

| Audit Report | | | | | | | | | |
|----------------------|-------------|---------|-----|-----------------------|------------|-----------------------------------|-----------|--|--|
| Protocol Audit Trail | | | | | | | | | |
| AUDIT_ID | PROTOCOL_ID | SPONSOR | STL | PROTOCOL_TITLE | PPGX_STUDY | PPGX_PROTOCOL_TITLE | CREATED_B | | |
| 985 | 61 | AIA | | Evaluation of STUDY-1 | X | DNALIMS | | | |
| 988 | 61 | AIA | | Evaluation of STUDY-1 | X | DNALIMS | | | |
| 991 | 61 | AIA | | Evaluation of STUDY-1 | X | DNALIMS | | | |
| 991 | 61 | AIA | | Evaluation of STUDY-1 | X | DNALIMS | | | |
| 993 | 61 | AIA | | Evaluation of STUDY-1 | | Genomic DNA isolation and DNALIMS | | | |
| 997 | 61 | AIA | | Evaluation of | | Genomic DNA isolation and DNALIMS | | | |
| 998 | 61 | PHO-001 | | Evaluation of | | Genomic DNA isolation and DNALIMS | | | |
| 999 | 61 | PHO-001 | | Evaluation of | | Genomic DNA isolation and DNALIMS | | | |
| 1000 | 61 | PHO-001 | | Evaluation of | | Genomic DNA isolation and DNALIMS | | | |
| 1001 | 61 | PHO-001 | | Evaluation of | | Genomic DNA isolation and DNALIMS | | | |
| 1002 | 61 | PHO-001 | | Evaluation of | | Genomic DNA isolation and DNALIMS | | | |
| 1003 | 61 | PHO-000 | | Evaluation of | | Genomic DNA isolation and DNALIMS | | | |
| 1004 | 61 | PHO-001 | | Evaluation of | | Genomic DNA isolation and DNALIMS | | | |

Fig. 10

Reporting

- ◆ Multiple Report Types
 - Genotype Results
 - DNA Integrity
 - Purification Results
 - Sample Lists
 - Audit Trails
- ◆ Flexible Reporting Output
 - Using Excel
- ◆ Customized Reporting
 - Using 3rd Party Tools

| DNA Purification Results | | | | | | | | | | Sponsor: |
|--------------------------|-----------|-------|-------------|------------|----------|-------|------|------|----------------|-----------------------|
| Study: | | | | | | | | | | Representative: |
| Test | | | | | | | | | | Investigator(s): |
| Study #: 999-xxx | | | | | | | | | | |
| Sample # | Storage # | µg/ml | Protocol | Start Vol. | DNA Vol. | Yield | A260 | A280 | Subject Number | Initial Date of Birth |
| | EA11111 | 0 | Sample test | 09/06/00 | 499 | 0 | 0 | 0 | 1-ka | 5/31/66 |
| | EA11112 | 0 | Sample test | 02/19/00 | 48 | 0 | 0 | 0 | 2-lhb | 8/2/67 |
| | EA11113 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 3-lsc | 5/22/66 |
| | EA11114 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 4-jmm | 4/11/74 |
| | EA11115 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 5-trv | 9/9/72 |
| | EA11117 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 1-ka | 5/31/66 |
| | EA11116 | 0 | Sample test | 09/06/00 | 96 | 0 | 0 | 0 | 2-lhb | 8/2/67 |
| | EA11118 | 0 | Sample test | 09/06/00 | 248 | 0 | 0 | 0 | 3-lsc | 5/22/66 |
| | EA11119 | 0 | Sample test | 09/06/00 | 582 | 0 | 0 | 0 | 4-jmm | 4/11/74 |

Fig. 11